

SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 3 2006

Assigned 510(k) Number

The assigned 510(k) number is K053533

Sponsor Name and Address

Diagnostic Products Corporation
Corporate Offices
5210 Pacific Concourse Drive
Los Angeles, CA
90045-6900
(310) 645-8200

Contact

Deborah L. Morris
Director, Clinical and Regulatory Affairs
(310) 645-8200 extension 7426
dmorris@dpconline.com

Device Name

Trade Name:	IMMULITE®/IMMULITE® 1000 <i>Turbo</i> Intact PTH
Common Name:	Intact Parathyroid Hormone Assay
Classification:	Class II device, CEW 21 CFR 862.1545
DPC Catalog Number:	LSKPTZ (50 tests)

Description of Device

IMMULITE/IMMULITE 1000 *Turbo* Intact PTH is a solid-phase, chemiluminescent immunometric assay employing a goat polyclonal anti-PTH (44-84) antibody as the capture antibody and a goat polyclonal anti-PTH (1-34) antibody conjugated to alkaline phosphatase as the detection antibody.

Indications for Use

“For *in vitro* diagnostic use with the IMMULITE and IMMULITE 1000 Analyzers — for the quantitative measurement of intact parathyroid hormone (parathyrin, PTH) in EDTA plasma or serum. It is intended as an aid in the differential diagnosis of hypercalcemia and hypocalcemia and can be used intraoperatively.”

Manufacturing Site

IMMULITE®/IMMULITE® 1000 *Turbo* Intact PTH assay is manufactured by Diagnostic Products Corporation at the following locations:

Diagnostic Products Corporation
Reagent Manufacturing Division
5700 West 96th Street
Los Angeles, CA 90045-5597
FDA Establishment #: 2017183

Diagnostic Products Corporation
Corporate Offices
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
FDA Establishment #: 3005250747

Performance Equivalence

Substantial equivalence assessment for intra-operative use of the IMMULITE/IMMULITE 1000 *Turbo* Intact PTH assay is based upon comparison to clinical data. The IMMULITE/IMMULITE 1000 *Turbo* Intact PTH assay kit has not changed from its original FDA clearance on July 6, 1999 (K992105). The IMMULITE/IMMULITE 1000 *Turbo* Intact PTH assay results were compared to clinical data when patient samples were tested in the IMMULITE/IMMULITE 1000 *Turbo* assay and results reported during parathyroid surgery. This comparison to clinical data was performed by two groups of researchers, Kao PC, et al. at the Mayo Clinic, Rochester Minnesota and Johnson LR, et al. at Washington University School of Medicine/Barnes Jewish Hospital, St. Louis, Missouri. Results were reported in peer reviewed journals.

Kao PC, van Heerden JA, Farley DR, et al. Intraoperative monitoring of parathyroid hormone with a rapid automated assay that is commercially available. Annals of Clin & Lab Science 2002;32(3):244-251.

Johnson LR, Doherty G, Lairmore T, et al. Evaluation of the performance and clinical impact of a rapid intraoperative parathyroid hormone assay in conjunction with preoperative imaging and concise parathyroidectomy. Clin Chem 2001;47(5):919-925.

Summary of Clinical Investigations

Clinical investigations using the IMMULITE/IMMULITE 1000 *Turbo* Intact PTH (parathyroid hormone) assay during parathyroid surgery were conducted by two groups of researchers, one at the Mayo Clinic, Rochester, Minnesota (Kao PC, et al.) and the second at University of Washington Medical School/Barnes Jewish Hospital, St. Louis Missouri (Johnson LR, et al.).

The researchers at the Mayo Clinic collected blood specimens from 47 parathyroid gland surgery patients during surgery. The schedule for specimen collection was at baseline (prior to removal of abnormal tissue) and 5, 10, and 20 minutes after beginning parathyroid resection. The generally accepted guideline that a 50% or greater decrease from the baseline PTH value suggests complete tumor removal was used. Among 47 parathyroidectomy patients tested with the IMMULITE/IMMULITE 1000 *Turbo* Intact PTH assay, 45 (96%) had their plasma intact PTH (iPTH) levels decrease to < 25% of baseline. A second criterion important for the surgeon is a return to normal iPTH values after parathyroid tissue is removed. This occurred in 87% of patients in this study and all of them were clinically cured. Collection of blood samples was stopped at 10 minutes in 2 patients and at 15 minutes in 2 patients making this test suitable for the intended intraoperative monitoring purpose.

The researchers at Washington University/Barnes Jewish Hospital examined the performance of the IMMULITE/IMMULITE 1000 *Turbo* iPTH assay intraoperatively in a study group of 49 patients and compared clinical outcomes to a “control” group of 55 patients that underwent parathyroidectomies without intraoperative PTH determinations. This study also employed the generally accepted guideline that a $\geq 50\%$ decrease in the iPTH value from baseline suggests complete tumor removal. Samples were drawn in the operating room before incision and during the period 10-12 minutes after excision of suspected diseased parathyroid gland tissue. Of the 49 patients in the study group, 46 had a > 50% decrease in iPTH values within the first three post-resection samples. When the control and study groups with similar sex, age, and diagnoses were compared, 44/49 (90%) of the patients in the study group and 49/55 (89%) of the control patients achieved normocalcemia postoperatively. Thus, the surgery guided by intraoperative IMMULITE/IMMULITE *Turbo* Intact PTH measurements had identical physiologic outcomes. Frozen section use in the study group was statistically significantly less ($p < 0.0001$) than in the control group.

Conclusions from Clinical Studies

When used intraoperatively (samples tested and results reported) for parathyroid surgery, the IMMULITE/IMMULITE 1000 *Turbo* Intact PTH assay provides surgeons with rapid, accurate results corresponding to clinical signs and outcomes. The assay met the generally accepted criterion of a > 50% decrease from baseline (before incision) with complete tumor removal.

IMMULITE/IMMULITE 1000 *Turbo* Intact PTH assay's performance including measuring range, precision, analytical sensitivity, and correspondence to clinical status, makes this test suitable for the intended intraoperative monitoring purpose.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 3 2006

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Deborah L. Morris
Director, Clinical and Regulatory Affairs
Diagnostic Products Corporation
5210 Pacific Concourse Drive
Los Angeles, CA 90045

Re: k053533
Trade/Device Name: IMMULITE®/IMMULITE® 1000 *Turbo* Intact PTH
Regulation Number: 21 CFR§ 1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: December 16, 2005
Received: December 20, 2005

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

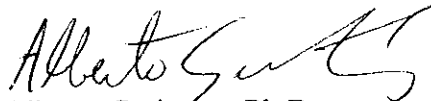
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 --

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053533

Device Name: IMMULITE®/IMMULITE® 1000 Turbo Intact PTH

Indications For Use:

"For *in vitro* diagnostic use with the IMMULITE and IMMULITE 1000 Analyzers — for the quantitative measurement of intact parathyroid hormone (parathyrin, PTH) in EDTA plasma or serum. It is intended as an aid in the differential diagnosis of hypercalcemia and hypocalcemia and can be used intraoperatively."

Prescription Use x

AND/OR

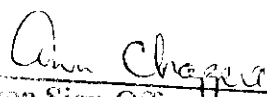
Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Ann Chagun
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

Page 1 of 1

510(k) K053533